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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,929	10/10/2006	Frederic Taran	279089US0PCT	6537

  

22850	7590	03/24/2010
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EXAMINER	
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ART UNIT	PAPER NUMBER
1641	

  

NOTIFICATION DATE	DELIVERY MODE
03/24/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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***Response to Election-Restriction***

1. Claims 27-29, 31, 33-35, 37, 38, 40, 42-45, 48, 49, 50, 51, 52 and 54 are pending and examined on merits in this office action.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 27-29, 31, 33-35, 37-38, 40, 42-45, 48-49 and 51-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27 and 54 recite “a compound Z comprising the chain  $E_1-X_1-G_1-G_2-X_2-E_2$  comprising  $E_1$ ,  $X_1$ ,  $\underline{E}_1$  and  $E_2$ ”. The recitation is vague and indefinite because it is unclear what compounds are intended to encompass by “chain  $E_1-X_1-G_1-G_2-X_2-E_2$  comprising  $E_1$ ,  $X_1$ ,  $\underline{E}_1$  and  $E_2$ ”? Does the second “comprising” term i.e. “comprising  $E_1$ ,  $X_1$ ,  $\underline{E}_1$  and  $E_2$ ” intended for further substitutions of the chain with the groups  $E_1$ ,  $X_1$ ,  $\underline{E}_1$  and  $E_2$ ? If it is so, where would be the substitutions? On  $E_1$ ,  $X_1$ ,  $G_1$ ,  $G_2$ ,  $X_2$  or  $E_2$  of the chain? The group  $E_1$  is recited twice after the second “comprising” and it is unclear why is  $E_1$  recited twice? Further it is unclear what other reaction products other than  $E_1-X_1-G_1-G_2-X_2-E_2$  are intended by the term “compound Z comprising the chain  $E_1-X_1-G_1-G_2-X_2-E_2$ ” generated from the reaction product of  $E_1-X_1-G_1$  and  $E_2-X_2-G_2$  because the term “comprising” is an open-ended word that, when used with a product (which is a compound) within a claim, makes the claim open-ended and indefinite and therefore, it is not possible to ascertain the metes and bounds of the

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claimed subject matter. The omission of failing to describe the claimed invention renders the claims incomplete. It is suggested to delete the expression "comprising" or amend the claims with in the context and scope of the claims in order to overcome the rejection.

4. Claims 50 and 51 recite "at least two compounds reacting together" in line 4. It is unclear what is intended to mean by "reacting together"? The term "reacting together" does not mean that the two compounds have reacted with each other or is capable of reacting with each other and it is unclear as to whether the term is intended for two compounds capable of reacting with each other? Further, what type of reaction is intended to encompass by the term "reacting"? "Reacting" does not indicate that they are capable of forming a bond (covalent bond). Further the compounds as recited in the claims disclose to have functional groups but it is not clear as to whether the "reacting" is intended for reaction of the functional group that are capable of forming a covalent bond or is intended for other type of reaction?
5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 27-29, 31, 33-35, 37, 38, 40, 42-45, 48, 49, 50, 51, 52 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The method of claim 27 is for screening the operating conditions of a coupling reaction of at least two functional group  $G_1$  and  $G_2$  by reacting compounds  $E_1-X_1-G_1$  and  $E_2-X_2-G_2$  having the functional group to provide the product  $Z$  having the formula  $E_1-X_1-G_1-G_2-X_2-E_2$  and determining the concentration of the product  $Z$  by an antibody recognizing  $E_1$ . However, the method steps as claimed in claim 27 will not be able to determine the concentration of product  $Z$  because the reaction mixture as recited in the claim would contain reaction product  $Z$  as well as un-reacted first compound  $E_1-X_1-G_1$  and un-reacted second compound  $E_2-X_2-G_2$ , all of which would react with the antibody  $AC_1$  (note that  $AC_1$  can form covalent bond with  $E_2$  in the presence of a coupling agent: see claim 27) and therefore, the method as recited would not be able to determine the concentration of compound  $Z$  without separation of the un-reacted compounds from the reaction mixture.

***Response to Applicant's argument***

7. Applicant's arguments and amendments filed 1/11/10 have been fully considered and are persuasive to overcome the rejections of 7/9/09 under 35 U.S.C. 112 second paragraph. However, Applicants arguments are not persuasive to overcome the rejection under 35 USC 112 first paragraph. Moreover, Applicants' amendments necessitated new ground of rejection as described in this office action.

Applicants urge that Applicants disclose a method comprising obtaining a compound  $Z$  in a reaction medium and subsequently determining the concentration of the obtained compound  $Z$  by using at least one immunoassay comprising at least the antibody  $AC_1$  as in amended Claim 27. In fact, Applicants further disclose that

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the at least one immunassay comprising the antibody AC<sub>1</sub> establishes immunobinding between the antibody AC<sub>1</sub> and the residue E1 of the compound Z and forms a covalent bonding of the antibody AC<sub>1</sub> and the residue of E2 of the compound Z, and Applicants also disclose details determining the concentration of compound Z from a conjugate attached to a solid phase by the antibody AC<sub>1</sub> in the reaction medium as in amended Claim 37.

However, the independent claim 27 does not have the limitation as Applicants urges. It is noted that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, as addressed in the rejection of 7/9/09, the method as claimed does not require separation of the un-reacted first compound E<sub>1</sub>-X<sub>1</sub>-G<sub>1</sub> which will react with antibody AC<sub>1</sub> and un-reacted second compound E<sub>2</sub>-X<sub>2</sub>-G<sub>2</sub> which will react with the antibody AC<sub>1</sub> in the presence of a coupling agent.

Applicants argued that Applicants show inventive examples of determining the concentration of the obtained compound Z in the reaction medium by at least one immunoassay comprising at least the antibody AC<sub>1</sub> (specification page 38, line 11 to continuing page 40, line 3) where there is no need to remove the un-reacted first compound E<sub>1</sub>-X<sub>1</sub>-G<sub>1</sub> from the reaction medium since the compound is not recognized by the antibody AC<sub>1</sub> and does not bind the conjugate.

However, as described in the specification, in order to use only one antibody specific for M<sub>1</sub>, the method requires AC<sub>1</sub> antibody immobilized on a solid support and

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an AC<sub>1</sub> antibody conjugated to a detectable label and the method further require the M<sub>2</sub> of the second compound be capable of forming at least one covalent bond with the AC<sub>1</sub> antibody that is immobilized on the solid support (see Fig. 3). Applicants are reminded that the reaction/coupling step of the M<sub>2</sub> to AC<sub>1</sub> after immobilization of the obtained compound Z through M<sub>1</sub> to the AC<sub>1</sub> and a reaction step to dissociate bound antibodies not coupled through a covalent bond after covalent bonding of M<sub>2</sub> to AC<sub>1</sub> (see page 18 and Fig. 3) are critical/essential steps to the practice of the invention using only AC<sub>1</sub> specific antibody. See MPEP 2172.01. Note that the phrase “comprising at least the antibody AC<sub>1</sub>” can be interpreted as being containing only AC<sub>1</sub> antibody. Further, Applicants argument that there is no need to remove the un-reacted first compound E<sub>1</sub>-X<sub>1</sub>-G<sub>1</sub> from the reaction medium since the compound is not recognized by the antibody AC<sub>1</sub> is contrary to what is described in the specification because specification clearly teach washing to remove un-reacted components (page 38, lines 16-18 and page 45, lines 3-5). Further as claimed, antibody AC<sub>1</sub> recognizes E<sub>1</sub> (i.e. residue of M<sub>1</sub>) of the compound E<sub>1</sub>-X<sub>1</sub>-G<sub>1</sub> and thus Applicants assertion that the compound E<sub>1</sub>-X<sub>1</sub>-G<sub>1</sub> is not recognized by AC<sub>1</sub> and does not bind the conjugate is unclear and does not find support in the specification.

Moreover, Applicants are reminded that E<sub>2</sub> in the elected second compound (compound VIII, see election of 3/23/09) represents a group capable of forming at least one covalent bond with the antibody AC<sub>1</sub> in the presence of a coupling agent and the method of detection/screening with this embodiment would encompass the critical/essential reaction/coupling step of the M<sub>2</sub> to AC<sub>1</sub> after immobilization of the

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obtained compound Z through  $M_1$  to the  $AC_1$  and a reaction step to dissociate bound antibodies not coupled through a covalent bond after covalent bonding of  $M_2$  to  $AC_1$  and thus the other embodiment(s) (method process) which requires the non-elected  $E_2-X_2-G_2$  (i.e. when  $M_2$  is different from  $M_1$  and for which a second specific antibody  $AC_2$  is available) have not been addressed/considered in the rejection as they encompasses non-elected embodiment(s).

### ***Conclusion***

8. Applicants' amendment necessitated new ground(s) of rejection presented in this office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicant should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support



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for the claimed invention (e.g., if the amendment is not supported in *ipsis verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Shafiqul Haq/  
Primary Examiner, Art Unit 1641